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7-19-13

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHEENA WILSON, individually and as Guardian of TT and TB (*Minor Children*)	:	Civil Action No. 13 CV 4327
	:	AMENDED COMPLAINT
Plaintiff,	:	JURY TRIAL DEMANDED
vs.	:	
INTUITIVE SURGICAL, INC.	:	
Defendant.	:	

Plaintiffs, complaining of the defendant by their attorneys, respectfully allege, upon information and belief, the following:

THE PARTIES

1. The plaintiff, Sheena Wilson, is a resident of and domiciled in Parlin, New Jersey. She is a single parent. TT and TB are two minor sons of plaintiff.

2. Plaintiff and minor children are residents of Parlin, New Jersey and are entitled to collect damages as a foreseeable result of defendant's conduct.

3. The defendant Intuitive Surgical, Inc. (hereinafter "Intuitive") is a foreign business corporation, duly organized and existing under and by virtue of the laws of the State of Delaware with a principle place of business in the State of California at 1266 Kifer Road, Building 100, Sunnyvale, CA 94086-5304.

JURISDICTION AND VENUE

4. Jurisdiction for this action in the United States District Court arises under 28 U.S.C. Sections 1332(a)(1) and 1332(c)(2) as this is a civil action based on complete diversity of citizenship in that the surgery performed on Sheena Wilson, a resident of New Jersey but a machine sold and distributed under the laws of Delaware by a corporation with its principle place of business in the State of California. The amount in controversy far exceeds $75,000 jurisdiction minimum, exclusive of costs and interest.

GENERAL ALLEGATIONS

5. Plaintiff was advised that she needed to have a hysterectomy performed.

6. Her physician, Dr. Brian Slomovitz of Morristown, New Jersey presented her with information and materials promoting the benefit of a da Vinci robotic hysterectomy over all other methods of surgery. Specifically, her physicians told her that due to the da Vinci robotic approach she would heal faster, have a better outcome and have less pain.

7. Based on representations made and the written material provided to her, the plaintiff agreed to proceed with the da Vinci robotic hysterectomy. She underwent the surgery on May 2, 2013, which resulted in damage, including significant post-operative intra-abdominal bleeding, thermal burning, severe infection with intra-abdominal abscesses and other medical complications and consequences requiring immediate further surgery on May 7, 2013.

8. Plaintiff continues to suffer from chronic abdominal pain, severe bowel issues and other issues. Through this time period Sheena Wilson has been unable to maintain normal parental relationships and responsibilities with her two sons, ages 11 and 14 respectively, who are totally dependant on her and she has suffered emotional distress and has not been able to resume her employment.

9. Due to the injuries sustained during the da Vinci robotic hysterectomy, plaintiff Sheena Wilson had to have multiple painful additional medical tests and procedures and physician consultations and additional surgery and has suffered pain, loss of function, emotional distress and permanent injury and will be suffering further substantial medical treatment and is disabled.

10. Defendant Intuitive Surgical Inc. ("Defendant") is Delaware corporation with its principal place of doing business in Sunnyvale, California.

11. Defendant Intuitive is a publically traded company on the NASDAQ exchange, with a current market value of more than two billion dollars.

12. Defendant designed, manufactured, tested, sold, promoted and labeled the da Vinci surgical robot.

13. On its website defendant asserts that it is the global technology leader in surgical robotic products and promotes and advertises its products extensively.

14. The said robotic devise has been used in hospitals for a variety of surgeries, including gynecological surgeries, which includes

hysterectomies.

15. Defendant has promoted its device as (a) safe and (b) safer than other comparative methods of surgery including, in the case of hysterectomies, laparoscopy, vaginal surgery and open surgery.

16. The defects in Defendant's products were inherent and existed at the time it left the Defendant's facilities.

17. Defendant utilizes prominent websites aimed at consumers, seeking to create demand and assurances for the use of its robotic device by patients who consult surgeons.

18. Defendant sold its device through a calculated program of intimidation and market management, forcing hospitals and physicians to purchase it in order to appear to be competitive, and creating a fear in their minds that if they did not have this technology they would lose business to competitors.

19. Defendant reinforced its calculated program, as stated in the preceding paragraph, by placing, on its website for potential patients, names of certain physicians who had performed surgeries with this device.

20. Hospitals have paid in excess of $1.5 million dollars for the

product, and more than 2500 such machines were marketed and sold by defendant prior to May 2012 plus five (5) year maintenance contracts at a cost of approximately $100,000 per year per machine.

21. The use of defendant's robotic device in surgery presents substantial risks of complications and injuries, including, but not limited to, de-vascularzation of the vaginal cuff impeding healing, partial thermal injury burns to bowel, post-surgical abscesses, tears, bleeding, hematomas, sepsis, fistulas and otherwise.

22. More specifically, defendant's robotic device can cause damage to the bowel, rectum, blood vessels, arteries, ureters, bladder and vaginal cuff.

23. On occasion these complications and injuries cause and/or contribute to infectious processes from thermal injury causing abscess formation and can lead to excessive pain, suffering and permanent emotional and physical disability.

24. Defendant has been aware and was aware long before May 2, 2012 of the aforesaid risks and complications associated with the use of the said robotic device and has failed to take proper precautions including failure to make property notifications to hospitals,

patients, doctors and the United States Food and Drug Administration.

25. Defendant Intuitive did not provide adequate warnings to physicians and patients about the risks and complications associated with the use of its robotic device.

26. Defendant Intuitive had not done and has not done adequate post marketing surveillance of complications and injuries that have occurred in actual practice and which were known to the defendant. During the trial periods referred to prior to plaintiff's surgery on May 2, 2013, which defendant and its executives were well advised and notified of the potential financial consequences of the defective da Vinci Robot mechanism shortly prior to May 2, 2013. Executive insiders sold off substantial holdings. By way of example, the Chairman of the Board sold off a substantial share of his personal stock interests for over $50 million.

27. Defendant has not done, nor sponsored any testing as to long-term outcomes in comparison to other surgical and laparoscopic methods.

28. Defendant had not revealed timely, through publications or reports

to the Food and Drug Administration and other governmental bodies, the true extent of complications and injuries, which then known to have been occurring in actual practice.

29. Defendant had been suppressing reports and complaints of complications and performance errors due to the use of its said device prior to plaintiff's surgery.

30. Defendant does not adequately train physicians nor proctor them properly on the use of its device, thereby inducing them to cause complications and injuries, which would be avoided in the hands of properly trained physicians.

31. Defendant represents that they will have skilled technicians in the operating room or on emergency call in the event of problems arising with its said device, but often has neglected to do so.

32. Defendant has over-promoted its device to hospitals, physicians and the public, including potential consumers, combined with minimizing the risks and complications associated with its use.

33. The da Vinci surgical robot was defective in that it relied upon the use of monopolar energy to cut, burn, cauterize tissue, whereas safer methods were available.

34. The device has inadequate insulation for its arms thereby allowing electrical current to pass into tissue outside of the operative field thereby causing extensive injury.

35. The insulation on the shafts of the said device had become torn and worn in places, without the awareness of the physician user allowing electrical current to pass into tissue outside of the operative field causing damage.

36. Defendant had failed to warn users and consumers of the said robotic device about the inadequate insulation on the arms and the potential for electrical current to pass into tissue outside of the operative field.

37. Due to design defects, defendant's devices had malfunctioned during the course of operative use causing injury, requiring additional surgeries and procedures to deal with complications of robotic use.

38. Defendant had failed to warn users and consumers of its said device of the design flaws stated in the preceding paragraphs, although it has reached out directly to consumers to promote its asserted advantages.

39. Defendant, in points of time, had specific knowledge and awareness of the dangers of monopolar current and that there were safety modalities commercially available that could have greatly diminished or eliminated some of these risks, yet the defendant elected not to include these safety features on the da Vinci Robotic Hysterectomy platform.

40. Defendant had obtained and continued to maintain approval of the uses of its device from the Food and Drug Administration by failing to fully inform them of its knowledge of risks and complications associated with the use of its device.

41. The plaintiff has had extensive surgeries and will be needing more extensive surgery and care and has had and will permanently have considerable loss of functions.

FIRST CAUSE OF ACTION-PRODUCT LIABILITY

42. Plaintiff incorporates by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

43. Defendant owed plaintiffs a duty to exercise reasonable care when designing, testing, manufacturing, marketing, advertising, promoting, distributing, and/or selling da Vinci Robots for

hysterectomy.

44. At all relevant times to this action, defendant owed a duty to properly warn plaintiff, the medical community and the public of risks, dangers and adverse side effects of the da Vinci Robotic hysterectomy platform as soon as it became known.

45. Defendant breached its duty by failing to exercise ordinary care in the preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of da Vinci Robotic Surgery, as set forth below:

a. Failing to test da Vinci Robotic Hysterectomy properly and thoroughly before promoting the robotic surgical platform using monopolar current to the market;

b. Failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of monopolar current used in the da Vinci Robotic Hysterectomy.

c. Failing to report to the Food and Drug Administration, the medical community, and the general public those data resulting from pre-and-post marketing tests of the da Vinci

Robotic Hysterectomy platform which indicated risks associated with its use;

d. Failing to conduct adequate post-market monitoring and surveillance of post-surgical complications associated with the da Vinci Robotic Hysterectomy platform using monopolar current;

e. Failing to conduct adequate analysis of adverse event reports and data and maintained a conscious disregard for his data;

f. Designing, manufacturing, marketing advertising, distributing and promoting the da Vinci Robotic Hysterectomy directly to consumers, including plaintiff, without adequate warning of the significant and dangerous risks of monopolar current and the da Vinci Robotic Hysterectomy platform and without proper instructions to avoid the harm which could foreseeably occur as a result of using monopolar energy on the existing da Vinci Robotic Hysterectomy platform.

g. Failing to exercise due care when advertising and promoting da Vinci Robotic Hysterectomy ;

h. Negligently continuing to manufacture, market, advertise and promote da Vinci Robotic Hysterectomy after defendant knew or could have known of the risks of serious injury and/or death associated with using monopolar current to perform certain aspects of the surgery;

i. Failing to use due care in the preparation and development of the da Vinci Robotic Hysterectomy to prevent the aforementioned risk of injuries to individuals through the use of monopolar current;

j. Failing to use due care in the design of the da Vinci Robotic Hysterectomy platform with special regard to the insulation of the robotic arms and instruments to prevent the aforementioned risk of injuries to individuals during the routine course of surgery;

k. Failing to conduct adequate pre-clinical testing and research to determine the safety of the use of monopolar current and the insulation of the robotic instruments to be used in robotic hysterectomy, with special regard to the reusing of the instruments up to ten time in ten different patients;

l. Failing to conduct adequate intra-operative surveillance and post-operative complication studies to determine the safety of the use of monopolar energy during the surgical robotic hysterectomy procedure taught by Intuitive Surgical, Inc. while defendant knew or should have known that intra-operative surveillance and post-operative complication analysis would be the only means to determine the relative risk of using monopolar when performing a robotic hysterectomy causing severe thermal injury to patients' bowel, vaginal cuff, and blood vessels, in the absence of clinical trials which cannot be conducted for this purpose, and that such surveillance would be necessary for a due diligence program that would have altered defendant to the need to change the technique for the use of monopolar current or to withdraw it from the market altogether prior to this plaintiff's surgical procedure.

m. Failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing of issues with monopolar energy and post-marketing surveillance of

monopolar energy related injuries and complications to plaintiff, consumers, the medical community and the Food and Drug Administration.

n. Failing to accompany marketing materials promoting the da Vinci Robotic Hysterectomy platform using monopolar current with proper warnings regarding all possible adverse side effects associated with the use of the same;

o. Failing to use due care in the manufacture, inspection and safety evaluation of the da Vinci Robotic Hysterectomy platform to prevent the aforementioned risk of injuries to individuals who underwent a da Vinci Robotic Hysterectomy;

p. Failing to use due care in the promotion of da Vinci Robotic Hysterectomy to prevent the aforementioned risk of injuries to individuals;

q. Failing to use due care in the promotion of da Vinci Robot to prevent the aforementioned risk of injuries to individuals who were to undergo robotic hysterectomy;

r. Failing to use due care in the selling of the monopolar

scissors to prevent the aforementioned risk of injuries to individuals who underwent da Vinci Robotic Hysterectomy;

s. Failing to provide adequate and accurate training and information to the sales representatives who sold the da Vinci Robot;

t. Failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of the da Vinci Robot for hysterectomy.

u. Failing to conduct or fund research into the development of safer robotic surgical instruments which would pose the least risk of causing severe thermal injury to bowel, bladder, ureter and blood vessels;

v. Failing to educate healthcare providers and the public about the safest use of the monopolar scissors in da Vinci Robotic surgery;

w. Failing to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient using the da Vinci Robotic Hysterectomy platform and technique featuring the use of monopolar current; and

x. Being otherwise reckless, careless and/or negligent.

46. Defendant placed into the stream of commerce its aforesaid device, which was defective in its labeling and warnings, as previously pleaded.

47. Defendant placed into the stream of commerce its aforesaid device, which was defective in its testing and approval, as previously pleaded and did not cause notification to plaintiff and others similarly situated until long after it had knowledge of the damages of the aforesaid robotic device and in this case not until after May 2, 2013 and after plaintiff's surgical procedures. (See **Exhibit A**).

48. At the time the device left the possession of defendant it was in an unreasonably dangerous and defective condition for application for robotic hysterectomy using monopolar energy.

49. Despite the fact that defendant knew or should have known that the da Vinci Robotic Hysterectomy platform using monopolar current had increased the risk of serious injury and/or death, defendant continued to promote and market the da Vinci Robotic Hysterectomy to consumers, including plaintiff Sheena Wilson, when safer and more effective methods of treatment were known

to be available.

50. The defendant designed, manufactured, packaged, marketed, distributed, promoted and sold the da Vinci Robot, placing the da Vinci Robotic Hysterectomy into the stream of commerce.

51. The da Vinci Robot was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by defendant in a defective and unreasonably dangerous condition to consumers, including plaintiff.

52. The da Vinci Robot was expected to reach, and did reach, users and/or consumers, including plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was manufactured and sold.

53. Plaintiff's surgeon used the da Vinci Robotic Hysterectomy platform including monopolar current as instructed by and certified by and in the foreseeable manner normally intended, recommended, promoted and marketed by defendant. Upon information and belief, plaintiff's surgeon attended a surgical lab for hands-on initial training and were proctored for by a proctor

employed by Defendant.

54. The da Vinci Robotic Hysterectomy platform was unreasonably dangerous in that, as designed, it failed to perform safely when used by ordinary consumers, including plaintiff's surgeon, including when it was used as intended and in a reasonably foreseeable manner.

55. The da Vinci Robotic Hysterectomy was unreasonably dangerous, in that, as designed, the risks of serious injury and/or death, including bowel, rectum, bladder, ureter, vaginal cuff, abscess formation, permanent scarring or vascular injury, posed by its monopolar current risks exceeded any benefit the robotic approach was designed to or might in fact bestow.

56. The da Vinci Robotic Hysterectomy platform was unreasonably dangerous, in that, as designed, it was dangerous to an extent beyond that contemplated by the medical community, and ordinary patients, including the plaintiff Sheena Wilson.

57. The da Vinci Surgical Robot was defective in its design, in that, it neither bore nor was packaged with, nor accompanied by, warnings adequate to alert the medical community, including

plaintiff's surgeon, to the risks described herein, including, but not limited to, the risk of serious injury and/or death, including bowel, bladder, ureter, vaginal cuff devascularization, or vascular injury. Posed by its monopolar current risks. The da Vinci Robot was not accompanied by adequate labeling, instructions for use and/or warnings to fully apprise the medical, hospital, operating room and/or scientific communities, and the potential patients, including plaintiff, of the potential risks and serious side effects associated with its use, thereby rendering defendant liable to the plaintiff.

58. There were safer alternative energy modalities available including bipolar energy and ultrasonic energy.

59. Monopolar energy, as used and taught on the da Vinci Robotic Hysterectomy platform, was unsafe for normal reasonably anticipated use in performing the colpotomy incision or the amputation of the uterus.

60. In light of the potential and actual risk of harm associated with the use of monopolar energy so close to bowel, bladder, ureter, vaginal cuff and blood vessels, a reasonable person who had actual

knowledge of this potential and actual risk of harm would have concluded that the da Vinci Robotic Hysterectomy platform should not have been marketed in that condition.

61. Although defendant knew or should have known of the defective nature of its da Vinci Robotic Hysterectomy platform using monopolar current, it continued to design, manufacture, market and promote the use of its da Vinci Robotic Hysterectomy platform so as to maximize sales and profits at the expense of the public health and safety. Defendant thus acted with conscious and deliberate disregard of the foreseeable harm caused by the continued use of monopolar energy on its robotic platform.

62. Plaintiff could not, through the exercise of reasonable care, have discovered the risk of serious injury and/or death associated with and/or caused by the da Vinci Robotic Hysterectomy platform featuring monopolar current. Plaintiff, if aware of these additional risks could have chosen surgical procedures with similar efficacies but without these additional risks. As a result, plaintiff suffered the personal injuries described herein.

63. Information given by defendant to the medical community and to

the consumers concerning the safety and efficacy of the da Vinci Robotic Hysterectomy platform, especially the information contained in the advertising and promotional materials, did not accurately reflect the serious and potentially fatal side effects and consequences.

64. Had adequate warnings and instructions been provided, plaintiff's surgeon and doctors would not have suggested a robotic approach, and plaintiff would have had a much lower risk of the harmful side effects described herein and/or could have made an informed judgment.

65. As a direct and proximate consequence of defendant's negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, the plaintiff Sheena Wilson and her children sustained injuries and damages alleged herein.

66. That by reason of the foregoing and defendant's aforesaid conduct, among other things, the plaintiff Sheena Wilson suffered injuries which caused her to undergo additional surgeries and medical procedures, endured pain and suffering and will continue to do so

in the future, has suffered mental anguish and will continue to do so in the future, has lost the pleasure of sexual activity, and has incurred medical expenses.

67. Plaintiff has incurred and defendant is liable for certain expenses, including hospital, surgical and medical treatment, transportation costs to various medical facilities as a result of, among other things, loss of income, pain and suffering as a result of defendant's conduct which was in conscious disregard of consequences.

68. As a result of its said conduct, defendant has become strictly liable to plaintiff.

69. Defendant's conduct in continuing to market, sell and distribute the aforesaid devices after obtain knowledge and consciously disregarding they were defective and not performing as represented and intended, showed complete indifference to and/or a conscious, wanton disregard for the safety of others justifying an award of punitive damages for aggravating circumstances in such a sum which will serve to deter defendant and other from similar conduct in the future.

WHEREFORE, plaintiffs, Sheena Wilson, TT and TB demand

judgment against defendant and seeks compensatory damages and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other further relief as this Court deems just and proper.

SECOND CAUSE OF ACTION-GENERAL NEGLIGENCE & NEGLIGENT TRAINING & PROCTORING & NEGLIGENT CERTIFICATION

70. Plaintiffs repeat, reiterate and reallege each and every allegation and cause of action contained herein as if the same were set forth more fully at length herein.

71. Defendant was careless in the design, testing, manufacturing, labeling and promotion of its aforesaid device, as pleaded in previous paragraphs.

72. In specific, defendant failed to warn users and consumers of the risk of complications associated with the use of its said device, risks of monopolar current use, including the damage to the bladder, bowel, ureter, vaginal cuff, and blood vessels; the bladder and ureter which was a proximate cause of plaintiff Sheena Wilson's additional surgery and medical treatments resulting in long term pain and suffering.

73. Upon information and belief, defendant took it upon itself to "train" and "certify" plaintiff's surgeon on the use of the da Vinci Robotic Hysterectomy platform using monopolar current. Upon information and belief, the defendant specifically trained plaintiff's surgeon Dr. Brian Slomovitz on the use of monopolar current via operative endo-shear scissors during the dissection of the bladder and the colpotomy incision causing thermal injury and devascularization of the vaginal cuff leading to increased tissue damage, abscesses, and chronic inflammatory changes.

74. Upon information and belief, defendant did not properly proctor and/or properly instruct plaintiff's surgeon and attending staff as to the sage use of its device nor how to detect complications which its said device causes and is known to cause.

75. Defendant had a financial incentive to promptly train, proctor and certify plaintiff's surgeon without regard to whether or not plaintiff's surgeon was truly skilled and competent on the da Vinci Robotic Hysterectomy platform.

THIRD CAUSE OF ACTION-FRAUD

76. Plaintiffs repeat, reiterate and re-allege each and every allegation

and cause of action set forth herein as if the same were set forth more fully at length herein.

77. Defendant misrepresented the safety and comparative efficacy of its device, upon which plaintiff's surgeons relied, to plaintiff's detriment.

78. Defendant misrepresented the safety and comparative efficacy of its device, upon which the hospital and surgery department where plaintiff was operated on relied, in purchasing and using the device to plaintiff's detriment.

79. Defendant was aware and/or should have been aware, of the known dangers of monopolar current in regard to unsuspected current leaving the shaft of a poorly insulted instrument. Furthermore, defendant suggested to hospitals that multiple uses of the robotic instruments could be done yet defendant did so without regard to re-testing of the insulation along the shaft of their robotic instruments or at the wrist of the robotic instrument.

80. Defendant was aware, or should have been aware, of the known dangers of monopolar current in regard to capacitive coupling, which like insulation failure can cause a thermal injury to occur in

adjacent structures like bowel, rectum, bladder, ureter, vaginal cuff, or blood vessel. Defendant was aware and with conscious disregard of the known increased incidence of vaginal cuff dehiscene, de-vascularization and abscess formation due to the use of monopolar current while performing the colpotomy portion of the da Vinci Robotic total laparoscopic hysterectomy.

81. Defendant was aware that there were safer energy modalities yet caused to be maintained teaching and the use of the monopolar current in the da Vinci Robotic Hysterectomy. Defendant did so based on not wanting to pay for the cost of having to license these safer energy technologies.

82. Upon information and belief defendant was also aware, or should have been aware, of the Active Electrode Monitoring System, or AEM Technology, which shields and monitors instruments continuously directing stray energy, the cause of stray electrosurgical burns, away from the patient. With the AEM system, the patient is never at risk for stray electrosurgical burns due to insulation failure and capacitive coupling. Despite having specific knowledge of this safety system the defendant chose not to

purchase it for the da Vinci Robotic Hysterectomy platform using monopolar current.

83. Further, defendant concealed from consumers and users, including those mentioned in the preceding paragraphs, the risks of complications of which it was aware, which would have been material to consumers and users in making the decision to use the said device.

84. Further, defendant suppressed reports of adverse outcomes with the use of its device, which would have been material to consumers and users in making the decision to use the said device.

85. Further, defendant over-promoted its device and minimized the risks, for the purpose of making sales of its device, its maintenance and the use of replaceable parts and skewed the cost-benefit ratio inaccurately in its favor.

86. The said conduct was so willful, wanton, malicious and reckless that it merits the imposition of punitive damages.

WHEREFORE, plaintiffs, Sheena Wilson, TT and TB demand judgment against defendant and seeks compensatory damages and exemplary and punitive damages together with interest, the costs of suit

and attorneys' fees and such other further relief as this Court deems just and proper.

FOURTH CAUSE OF ACTION-FRAUDULENT CONCEALMENT

87. Plaintiffs hereby incorporate by reference all previous paragraphs of this complaint as if fully set forth herein and further alleges as follows:

88. Defendant had the duty and obligation to disclose to plaintiff and to her physicians the true facts concerning the da Vinci Robotic Hysterectomy platform , that is, that the da Vinci Robot was dangerous and defective and was likely to cause serious health consequences to users, including injuries as described in this complaint.

89. Defendant concealed important facts from plaintiff and from plaintiff's physicians which facts include, but are not limited to, that defendant had received numerous adverse events reports of serious injuries and/or death, including burns, tears, dehiscences, bleeding, hematomas, sepsis and fistulas prior to plaintiff's surgery on May 2, 2013.

90. Defendant made affirmative representations to plaintiff and her

physicians that the da Vinci Robotic Hysterectomy platform was safe as set forth above while concealing the material facts set forth herein.

91. Defendant Intuitive had the duty and obligation to disclose to plaintiff and to her physicians the true facts concerning the da Vinci Robotic Hysterectomy platform which facts include, but are not limited to, serious injuries and/or death including burns, tears, dehiscences, bleeding, hematomas, sepsis and fistulas prior to plaintiff's surgery at Overlook Hospital located in Summit, New Jersey, on May 2, 2013.

92. Defendant intentionally, willfully, and maliciously concealed or suppressed the facts set forth above from plaintiff's physicians and Overlook Hospital and therefore from plaintiff with the intent to defraud as alleged herein.

93. Neither plaintiff nor her physicians were aware of the concealed facts set forth herein. Had they been aware of those facts. They would have not acted as they did, that is, that the da Vinci Robotic Hysterectomy platform would not have been the chosen surgical modality of plaintiff and her physicians.

94. The plaintiff was denied the right to be informed of the numerous adverse events including serious injuries including burns, tears, dehiscences, bleeding, hematomas, sepsis and fistulas associated with the da Vinci Robotic Hysterectomy platform and plaintiff would have opted for a different surgical procedure if put on notice of adverse events known to defendant.

95. As a proximate result of the concealment or suppression of the facts set forth above plaintiff and her physicians' reasonably relied on defendant Intuitive's deception, and plaintiff underwent surgery utilizing the da Vinci Robotic Hysterectomy platform and subsequently sustained injuries and damages as set forth in this complaint. Defendant Intuitive's concealment was a substantial factor in causing plaintiff's injuries.

96. In doing the acts herein alleged, defendant Intuitive acted with oppression, fraud and malice and plaintiff is entitled to punitive damages in an amount reasonably related to plaintiff's actual damages and to defendant Intuitive 's wealth and sufficiently large to be an example to others and to deter defendant Intuitive and others from engaging in similar conduct in the future.

WHEREFORE, plaintiffs, Sheena Wilson, TT and TB demand judgment against defendant and seeks compensatory damages and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other further relief as this Court deems just and proper.

FIFTH CAUSE OF ACTION-BREACH OF EXPRESS WARRANTY

97. Plaintiffs repeat, reiterate and re-allege each and every allegations and cause of action set forth herein as if the same were set forth more fully at length herein.

98. Defendant made express warranties of safety to the buyers and consumers of the device utilized during plaintiff Sheena Wilson's surgery, upon which the buyers and users as agents of plaintiff Sheena Wilson relied, to her detriment. Defendant expressly caused to be represented to the plaintiff, Sheena Wilson (and to other consumers and the medical community) that the da Vinci Robotic Hysterectomy was safe, efficacious and fit for its intended purposes that it was of merchantable quality, that it did not produce un-warned of dangerous side effects and that it was adequately tested.

99. Defendant breached expressed warranties with respect to the da Vinci Robotic Hysterectomy in the following ways:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, surgeon training sessions, publications, notice letters, and regulatory submissions that the da Vinci Robotic Hysterectomy was safe, and fraudulently withheld and concealed information about the substantial risks or serious injury and/or death associated with using monopolar current on the existing da Vinci Robotic Hysterectomy platform;

b. Defendant represented that the da Vinci Robotic Hysterectomy was a safe and/or safer than alternative surgical methods, and fraudulently concealed information which demonstrated that the da Vinci Robotic Hysterectomy approach was not safer than alternatives available on the market, and;

c. Defendant represented that the da Vinci Robotic Hysterectomy was more efficacious than other alternative

surgical methods, and fraudulently concealed information that it was not more efficacious than alternative surgical methods.

100. The da Vinci Robotic Hysterectomy does not conform to defendant's express representations, because it is not safe, efficacious, has numerous serious un-warned of side effects, causes severe and permanent injuries including death, and was not adequately tested.

101. The da Vinci Robotic Hysterectomy including the use of monopolar current did not perform as safely as an ordinary physician, as an agent of the patient, would have expected when used as intended or in a reasonably foreseeable manner.

102. Plaintiff Sheena Wilson, her surgeons and others in the medical community, relied upon defendant's express warranties, resulting in the plaintiff's da Vinci Robotic Hysterectomy.

103. Plaintiff, after ascertaining through her own injuries that the da Vinci Robotic Hysterectomy violated express warranties, hereby supply notice to defendant of same through the filing of this lawsuit.

104. As a direct and proximate consequence of defendant's breach of express warranty and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, the plaintiffs sustained injuries and damages alleged herein.

105. By selling the said device, defendant made implied warranties of safety, merchantable quality and fitness for use, which was breached when plaintiff Sheena Wilson was injured during surgery.

106. As a further direct and proximate result of the acts of defendant, plaintiffs' suffered emotional distress.

WHEREFORE, plaintiffs demand judgment against defendant and seeks compensatory damages and exemplary and punitive damages together with interest, the costs of suit and attorneys fees and such other and further relief as this Court deems just and proper.

SIXTH CAUSE OF ACTION-BREACH OF IMPLIED WARRANTY

107. Plaintiffs incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

108. At all time relevant and material times, defendant manufactured,

distributed, advertised promoted and sold the da Vinci Robot.

109. At all relevant times, defendant intended that the da Vinci Robot be used in the manner that the plaintiff's surgeon in fact used it and defendant impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested.

110. Defendant breached various implied warranties with respect to the da Vinci Robot including the particulars:

a. Defendant represented through it labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters and regulatory submissions that the da Vinci Robotic Hysterectomy platform was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with the using the da Vinci Robot with monopolar current;

b. Defendant represented that the da Vinci Robotic Hysterectomy with monopolar current was as safe and/or safer than other alterative surgical approaches that did not include the use of da Vinci Robot, and fraudulently

concealed information, which demonstrated that the da Vinci Robotic Hysterectomy was not safer than alternatives available on the market; and

c. Defendant represented that the da Vinci Robotic Hysterectomy was as more efficacious than other alternative surgical approaches and techniques and fraudulently concealed information, regarding the true efficacy of the robotic hysterectomy with monopolar current.

111. In reliance upon defendant's implied warranty, plaintiffs surgeon used the da Vinci Robotic Hysterectomy platform as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed and marketed by defendant.

112. Defendant breached its implied warranty to plaintiff in that the da Vinci Robotic Hysterectomy platform with monopolar current was not of merchantable quality, safe, and fit for its intended use, or adequately tested.

113. As a direct and proximate consequence of defendant's breach of implied warranty and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described

herein, the plaintiff sustained injuries and damages alleged herein including pain and suffering.

114. As a further direct and proximate result of the acts of defendant, plaintiffs suffered emotional distress and loss of consortium.

WHEREFORE, plaintiffs demand judgment against defendant and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

SEVENTH CAUSE OF ACTION-UNJUST ENRICHMENT

115. Plaintiffs incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

116. At all times relevant to this action, defendant designed, advertised, marketed, promote, manufactured, distributed, supplied, and/or sold the da Vinci Robot for hysterectomy use.

117. Plaintiff Sheena Wilson's surgeon's hospital purchased the da Vinci Robot from the defendant for the purpose of using it for Robotic Hysterectomy. Same hospital purchased disposable and reusable instrument for the performing of Sheena Wilson's surgery.

118. Defendant accepted payment from said aforementioned hospital

for both the da Vinci Robot used in Sheena Wilson's surgery, but also for the routine maintenance and per surgery cost of additional items including disposable items.

119. Sheena Wilson did not receive the safe and effective surgical product which she intended to have been purchased; nor did the hospital where Sheena Wilson had her surgery.

120. It is inequitable and unjust for defendant to retain this money because the plaintiff did not in fact receive the safe and efficacious surgical procedure defendant represented da Vinci Robotic Hysterectomy to be.

WHEREFORE, plaintiffs demand judgment against defendant and seeks equitable relief, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

EIGHTH CAUSE OF ACTION-LOSS OF CONSORTIUM

121. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

122. As a direct consequence of the injuries to the abdomen and subsequent abscess and chronic inflammation and scarring sustained by Sheena Wilson while undergoing a da Vinci Robotic

Hysterectomy and the pelvic pain, formation of intra-abdominal abscesses, septic shock, and pain, permanent scarring and the emotional consequences ; plaintiff and her children have been deprived the normal companionship, company, affection, regard, assistance, comfort, personal relations, and emotional stability from Sheena Wilson.

123. These physical and emotional consequences of the injuries have negatively impacted the quality and caused undue hardship to that relationship.

WHEREFORE, plaintiff demands judgment against defendant and seeks compensatory damages and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff demand a trial by jury on all counts and issues so triable.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, plaintiffs respectfully demand judgment against defendant on each count as follows for compensatory and punitive damages, counsel fees and costs for:

a. On the First Cause of Action for Product Liability including

personal injury and pain and suffering and emotion distress;

b. On the Second Cause of Action for Negligence;

c. On the Third Cause of Action for Fraud;

d. On the Fourth Cause of Action for Fraudulent Concealment;

e. On the Fifth and Sixth Cause of Action for Breach of Express Warranty and Breach of Implied Warranty;

f. On the Seventh Cause of Action for Unjust Enrichment;

g. On the Eighth Count of Loss of Consortium of plaintiff and her children;

h. On the claim for punitive damages in each cause of action;

i. Reasonable attorney's fees; and

j. Such other additional and further relief to which plaintiff may be just entitled, in law or equity.

All together with the interest, cost and disbursements of this action.

Franzblau Dratch, P.C.
Attorneys for Plaintiff

By:_____
S. M. Chris Franzblau
354 Eisenhower Parkway
Plaza I
Livingston, New Jersey 07039
(973) 992-3700

Dated: July 19, 2013

Exhibit A

INTUITIVE SURGICAL®

May 08, 2013

Urgent Medical Device Notification - 2955842-05-07-2013-005

Intuitive Surgical *EndoWrist*® Instrument Hot Shears™ Monopolar Curved Scissors

AFFECTED PRODUCT:

PART NUMBERS	DESCRIPTION
420179-09 and -10	8 mm Monopolar Curved Scissors (a.k.a. Hot Shears)
400179-09 and -10	8 mm Monopolar Curved Scissors (a.k.a. Hot Shears)

Dear *da Vinci* Customer,

This notification is to inform you that Intuitive Surgical has identified a potential issue with certain versions of its **Hot Shears™ Monopolar Curved Scissors** (MCS) Instrument and to inform you of precautionary steps you should take to ensure the safety of patients, while using your current inventory of MCS Instruments.

Certain -09 and -10 versions of the MCS Instruments may develop micro-cracks near the distal (scissor) end of the shaft following reprocessing. This may create a pathway for electrosurgical energy to leak to tissue during use and potentially cause thermal injury. The affected area is shown in **Figure 1** below and is confined to an approximately 1 cm section of the shaft, as indicated. **These micro-cracks may not be visible to the user.**

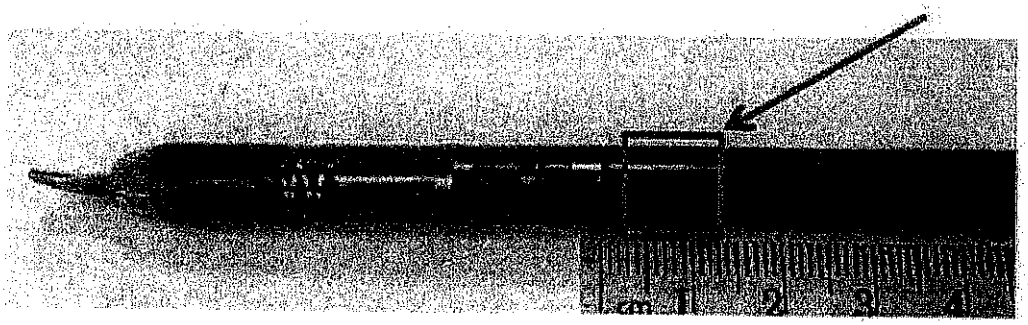

Figure 1: Location of micro-cracks

Our analysis shows only one complaint of an injury associated with use of an MCS instrument that was later found to have micro-cracks; however, laboratory testing did not detect any energy leakage from this instrument. The U.S. Food and Drug Administration (FDA) has been notified of this action. Please follow the instructions for use supplied with the product as well as observe each of the attached precautions noted in Attachment A.

The version number of the MCS instrument can be found printed on the box label or the printed side of the blue instrument housing as indicated in **Figure 2** below.

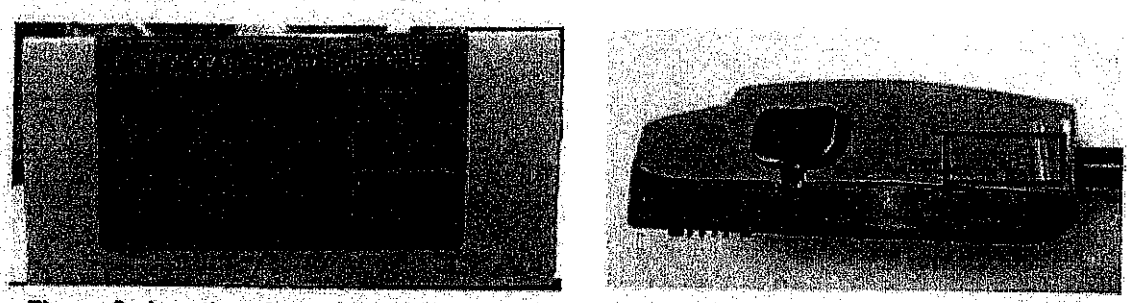

Figure 2: Location of version number on MCS instrument and box label

Important Note: No other Intuitive Surgical instruments are subject to this medical device notification.

Please Take the Following Actions:

1. **Forward this letter** to other managers within your facility (e.g., Risk Management, OR Director) who should be informed of this medical device notification.
2. **Review Attachment A for precautionary recommendations** and labeling reminders for usage of the MCS during surgery and the proper usage of electrosurgical units.

We will follow this email communication with a hard copy letter and an Acknowledgement Form, sent via express mail to your site.

We apologize for the inconvenience associated with this issue. We will immediately inform you when EndoWrist Hot Shears Monopolar Cautery Scissors without the potential for micro-cracks are available for replacement.

Should you have any further questions or require additional assistance, please contact Customer Service:

- North and South America: **800-876-1310** Option 3 (6 am to 5pm PST)
- Japan: **0120-56-5635** or **003-5575-1362** (9am to 6pm JST)
- Korea: **02-3271-3200** (9am to 6pm KST)
- Europe, Middle East, Asia and Africa: **+800 0821 2020** or **+41 21 821 2020** (8 am to 6 pm CET)

Sincerely,

Richard Reeves
Vice President, Regulatory Affairs
Intuitive Surgical, Inc.
1266 Kifer Road, Building 101
Sunnyvale, CA 94086-5304

European Office
Intuitive Surgical, Sàrl
1 Chemin des Mûriers
1170 Aubonne, Switzerland

Attachment A

Precautions and Warnings for Usage of the EndoWrist Monopolar Curved Scissors

• **Do not apply energy when scissor tips not in contact with tissue:** Energy should not be applied to an instrument when it is not in direct contact with tissue (referred to as "air-firing"). Additionally, do not use an electrosurgical instrument to apply cautery to any other instrument.

• **Be aware of critical anatomy in contact with the instrument during energy activations:** While activating

• **Be aware of critical anatomy in contact with the instrument during energy activation:** While activating monopolar energy, be aware of anatomy that is in contact with the instrument wrist or shaft. The instrument should not be used as a retractor while applying energy.

• **Survey the surgical field:** During each procedure, surgeons should survey the surgical field, particularly where the distal end of the instrument shaft may have been in contact with tissue. Survey tissue surrounding the main surgical field, including areas "below" or "behind" the cannula and endoscope that are normally outside the field of view.

• **Consider patient condition:** Before using monopolar cautery in a procedure, consider factors that may make a patient's anatomy and tissue more susceptible to injury from the application of cautery (e.g. patients that have received radiation therapy prior to surgery).

• **Only use a validated ESU:** The ESUs that have been validated for use with the EndoWrist monopolar instruments, including the MCS, are provided in section 3.1 in the Instruments and Accessories User Manual.

• **Do not exceed maximum monopolar cautery settings:** Guidelines on the maximum cautery settings are listed in section 3.3, Electrosurgical Unit (ESU) Settings and Energy Activation Cables, in the Instruments and Accessories User Manual. Exceeding the maximum cautery settings will exceed the 3kV limit for an instrument, which may result in electrical arcs and alternate site thermal injuries. The user manual also instructs users to set the power as low as possible to achieve adequate hemostasis. Refer to the general precautions and warnings in section 3.3 in the Instruments and Accessories User Manual.

• **Refer to the general precautions and warnings in sections 2.1, 2.2, 4.1, and 4.2 in the Instruments and Accessories User Manual.**

Field Notification Number: 2955842-05-07-2013-005